

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0001] (formerly 03D-0001)

DDM	2-14-06
Submission Date	2-15-06
Director	D. Hawkins

Guidance for Industry on Nonclinical Safety Evaluation of Pediatric Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Nonclinical Safety Evaluation of Pediatric Drug Products." This document provides guidance on the role and timing of animal studies in the nonclinical safety evaluation of therapeutics intended for the treatment of pediatric patients. The guidance discusses some conditions under which juvenile animals can be meaningful predictors of toxicity in pediatric patients and makes recommendations on nonclinical testing.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://>

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/www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Karen L. Davis Bruno, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3108, Silver Spring, MD 20993-0002, 301-796-2290.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Nonclinical Safety Evaluation of Pediatric Drug Products.” Many therapeutics marketed in the United States and used in pediatric patients lack adequate information in the labeling for use in that population. Recent FDA regulations have focused attention on current practices for evaluating drug safety in this population. Traditionally, safety data from clinical studies in adults, supported by nonclinical studies in adult animals, have been used to support the use of a drug in pediatric patients. These studies may not always assess possible drug effects on developmental processes specific to pediatric age groups. Some effects may be very difficult to detect in clinical trials or during routine postmarketing surveillance.

In the **Federal Register** of February 3, 2003 (68 FR 5301), FDA announced the availability of a draft version of this guidance entitled “Nonclinical Safety Evaluation of Pediatric Drug Products.” Interested persons had the opportunity to submit comments. Based on the public comments received, changes to wording have been added for clarity and the guidance has been finalized. This document provides guidance on the role and timing of animal studies in the safety evaluation of therapeutics intended for the treatment of pediatric

patients. It is intended to serve as a resource for general considerations in testing and provide specific recommendations based on available science and pragmatic considerations. The scope of this guidance is limited to safety effects that cannot be reasonably, ethically, and safely assessed in pediatric clinical trials.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on nonclinical safety evaluation of pediatric drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 2/8/06
February 8, 2006.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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